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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/529,654	04/18/2000	James T Loch III	3525-74	8308
22466	7590 09/22/2004		EXAM	INER
110110122	NECA PHARMACEU	STOCKTON, LAURA LYNNE		
GLOBAL IN	ITELLECTUAL PROPE ORD PIKE	RTY	ART UNIT	PAPER NUMBER
	ON, DE 19850-5437		1626	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<del></del>		Application No.	Applicant(s)			
		09/529,654	LOCH III ET AL.			
	Office Action Summary	Examiner	Art Unit			
		Laura L. Stockton, Ph.D.	1626			
	The MAILING DATE of this communication apor Reply					
THE - Exte after - If the - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR REPI MAILING DATE OF THIS COMMUNICATION. nsions of time may be available under the provisions of 37 CFR 1. SIX (6) MONTHS from the mailing date of this communication. e period for reply specified above is less than thirty (30) days, a rep period for reply is specified above, the maximum statutory period are to reply within the set or extended period for reply will, by staturely received by the Office later than three months after the mailined patent term adjustment. See 37 CFR 1.704(b).	. 136(a). In no event, however, may a reply ply within the statutory minimum of thirty (3 to will apply and will expire SIX (6) MONTHS te, cause the application to become ABAN	by be timely filed  10) days will be considered timely.  S from the mailing date of this communication.  DONED (35 U.S.C. § 133).			
tatus						
1)⊠	Responsive to communication(s) filed on <u>30 June 2004</u> .					
2a) <u></u> □						
3)[	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
	closed in accordance with the practice under	Ex parte Quayle, 1935 C.D. 1	1, 453 O.G. 213.			
ispositi	ion of Claims		•			
·	Claim(s) 44-69 is/are pending in the application	on.				
	4a) Of the above claim(s) is/are withdra					
	Claim(s) <u>57-69</u> is/are allowed.					
6)⊠	Claim(s) <u>44,47,49,51-53,55 and 56</u> is/are rejected.					
7)🖂	Claim(s) 45,46,48,50 and 54 is/are objected t	<b>0.</b>				
8)□	Claim(s) are subject to restriction and/	or election requirement.				
Applicati	ion Papers					
9)	The specification is objected to by the Examin	er.				
10)	The drawing(s) filed on is/are: a) ac	cepted or b) ☐ objected to by	the Examiner.			
	Applicant may not request that any objection to the	e drawing(s) be held in abeyance	. See 37 CFR 1.85(a).			
	Replacement drawing sheet(s) including the correct	ction is required if the drawing(s)	is objected to. See 37 CFR 1.121(d).			
11)	The oath or declaration is objected to by the E	xaminer. Note the attached O	ffice Action or form PTO-152.			
riority ι	under 35 U.S.C. § 119					
12)	Acknowledgment is made of a claim for foreign	n priority under 35 U.S.C. § 1	19(a)-(d) or (f).			
	☐ All b)☐ Some * c)☐ None of:	. •	_			
	1. Certified copies of the priority documen	ts have been received.	•			
	2. Certified copies of the priority documen		ication No			
	3. Copies of the certified copies of the price	ority documents have been rec	ceived in this National Stage			
	application from the International Burea					
* S	See the attached detailed Office action for a list	t of the certified copies not rec	eived.			
ttachmen						
	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948)		mary (PTO-413) ail Date			
	nation Disclosure Statement(s) (PTO-1449 or PTO/SB/08		mal Patent Application (PTO-152)			
	r No(s)/Mail Date	6) Other:	• • • • • • • • • • • • • • • • • • • •			

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#### **Detailed Action**

Claims 44-69 are pending in the application.

# Continued Prosecution Application

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on June 30, 2004 has been entered.

## Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 52 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 52, the phrase "according to any one of claim 51" is unclear since there is only one dependent claim listed. It is suggested that the phrase be changed to "according to claim 51".

## Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 44, 47, 49, 51, 53, 55 and 56 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,110,914 and claims 1-8 and 11 of U.S. Patent No. 6,706,878. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claimed compounds are generically described in the claims of each of the patents. See formula I in claim 1 in column 37, and the compound in column 38, lines 56-57 under claim 8 of '914; and formula I in claim 1 in column 35 and the compound in column 37, lines 3-4 under claim 9 of '878.

The indiscriminate selection of "some" among "many" is *prima facie* obvious, *In re Lemin*, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., treating psychotic disorders).

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One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating, for example, psychotic disorders. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

<sup>(</sup>a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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Claims 44, 47, 49, 51, 53, 55 and 56 are rejected under 35 • U.S.C. 103(a) as being unpatentable over Phillips et al. {U.S. Pat. 6,110,914}.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicants claim spiroazabicyclic heterocyclic compounds. Phillips et al. teach spiroazabicyclic heterocyclic compounds that are structurally similar to the instant claimed compounds. Note especially the compounds in column 3, lines 42-43; and in column 4, lines 23-24.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the compounds of the prior art and the compounds instantly claimed is that the instant claimed compounds are generically described in the prior art.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

The indiscriminate selection of "some" among "many" is *prima facie* obvious, *In re Lemin*, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally

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similar compounds would possess similar activity (e.g., treating psychotic disorders).

One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating, for example, psychotic disorders. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

#### Response to Arguments

Applicants' arguments filed June 30, 2004 have been fully considered. Applicants argue that a *prima facie* case of obviousness has not been established. Applicants argue that Phillips et al. only provide for single specie of RN 220100-73-2 and RN 220100-57-2 (both shown below) but the reference does not provide any motivation or suggestion to make the instant claimed compounds.

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RN 220100-73-2 REGISTRY
Spiro[1-azabicyclo[2.2.2]octane-3,2'(3'H)-füro[2,3-b]pyridin]-4'-amine,
n-phenyl- (9CI) (CA INDEX NAME)

FS 3D CONCORD
MF C19 H21 N3 0

SR CA
LC STN Files: CA, CAPLUS, USPATFULL
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Applicants' arguments have been considered but have not been found persuasive. As stated above, Phillips et al. teach spiroazabicyclic heterocyclic compounds that are structurally similar to the instant claimed compounds. Phillips et al. teach that the spiroazabicyclic heterocyclic compounds are useful in treating psychotic disorders. The compound in Phillips et al. found in column 3, lines 42-43 is the same compound found in the proviso at the end of instant claim 44. However, Phillips et al. teach that a group, such as a substituted amine group, represented by R<sup>2</sup>, R<sup>3</sup> and R<sup>4</sup> in Phillips et al. can be present not only at the 5-position of the spiroazabicyclic heterocyclic compound but also at the 4-position and the 6-position of the spiroazabicyclic heterocyclic compound as shown by the compounds in column 4, lines 37-40 in

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Phillips et al. Therefore, a compound such as the last compound on page 6 of the Response filed June 30, 2004 (instant claim 55), would have been obvious to one skilled in the art.

### Allowable Subject Matter

Claims 45, 46, 48, 50 and 54 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 57-69 are allowed over the art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Official fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

September 20, 2004